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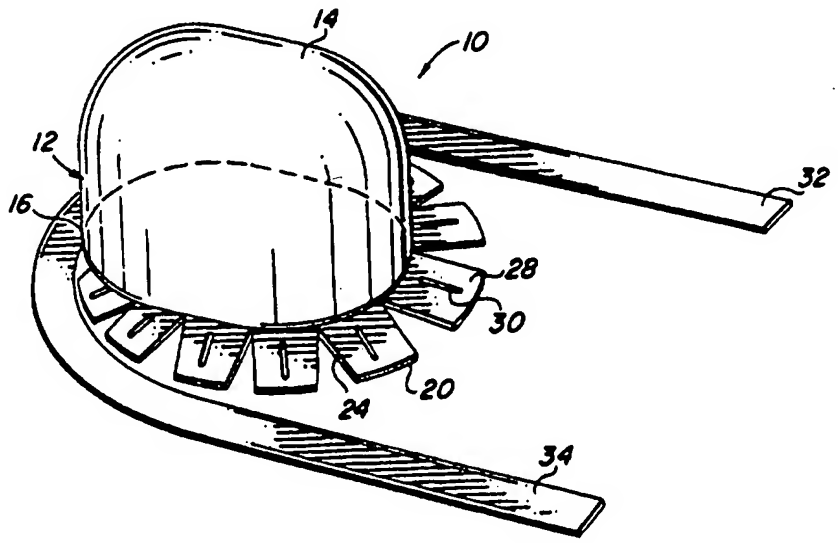
(54) Title: SURGICAL DEVICE FOR PROTECTING ORGANS FROM FORMATION OF ADHESIONS

(57) Abstract

A cover (10) for protecting and isolating an internal body organ or tissue to prevent post operative adhesions. The cover (10) is a nonresorbable material having a pouch pre-formed into a shape incorporating at least one compound curve conforming to the shape of the organ to which it is to be attached. The cover has integral ties (32, 34) which are surgically tensioned to secure the cover in place. The cover (10) is preferably fabricated from porous polytetrafluoroethylene (PTFE) which is die formed and heated to lock the pouch (12) in the desired shape.



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Title of the Invention

SURGICAL DEVICE FOR PROTECTING ORGANS FROM FORMATION OF ADHESIONS

Field of the Invention

The present invention relates to a cover for protecting and isolating an internal organ or body tissue from surrounding organs or tissue and more particularly relates to a protective pouch of non-resorbable material which is pre-formed to conform to the shape of an ovary or other organ or tissue to protect the organ from adhesion sequelae.

Background of the Invention

Adhesions are scar tissue that binds anatomical surfaces which surfaces are normally separated from each other. Adhesions are most commonly found in the abdominal area where they form after surgery, inflammation or injury and cause abdominal pain, nausea, vomiting, distention. In some cases corrective surgery such as an adhesiotomy is necessary to remove adhesions.

Formation of adhesions can result in special medical problems in the field of infertility. The ovary is the center of focus in the field of infertility medicine. Conception depends upon the availability and migration of a single cell (the ovum) from the surface of the ovary into the fallopian tubes. Physicians are very concerned and very aggressive in protecting the ovary and keeping the ovary free from any conditions that would negatively impact this process. See Bronson, R.A.,

Wallach, E.E. Lysis of Periadnexal Adhesions for Correction of Infertility, "Fertility Sterility" 28:613-619

Because the presence of adhesions on the surface of the ovary or a cyst within its mass may prevent or hinder proper ovulation, removal of adhesions and cysts has received attention in the field of gynecologic surgery. However, surgical treatment of adhesions and cysts often leads to further adhesion formation causing post operative ovarian abnormalities which, in some instances, are themselves as detrimental as those conditions which the initial surgery attempted to correct. Loss of ovarian epithelium, ischemia of the site due to the use of cautery to maintain hemostasis and the use of non-inert foreign bodies as a suturing material all create conditions that contribute to the formation or recurrence of adhesions on the ovarian surface.

In attempting to manage peritoneal adhesions, physicians have investigated various strategies and treatments to prevent these post operative sequelae. These strategies and treatments have included the use of liquid adjuvants such as dextran preparations, carboxymethyl cellulose and Ringer's lactate solution. Other techniques such as drug therapy utilizing topical antibiotics, glucocortoids and non-steroidal anti-inflammatories have been investigated.

Another approach has been the use of biologic or man-made barriers to isolate an internal organ or tissue to protect against adhesion formation. The latter includes amnion, mesentery, free peritoneal grafts, gold leaf, petroleum jelly

and other such exotica. However, none of the above strategies or procedures have been shown to be efficacious in the prevention of ovarian adhesions.

Presently there are two barrier adjuvants that have been experimentally and clinically demonstrated to be effective. One adjuvant comprises a barrier of oxidized regenerated cellulose (ORC), and another comprises porous polytetrafluoroethylene (PTFE). ORC has been shown to be ineffective in the presence of all but exacting hemostasis and may, in fact, be adhesiogenic due to its acidic nature and the brisk foreign body response it engenders. Porous polytetrafluoroethylene, in contrast, may be used in conditions that are not perfectly hemostatic and porous polytetrafluoroethylene has the characteristic of being one of the most inert biomaterials developed to date. However, prior work with ORC and porous polytetrafluoroethylene as physical barriers to prevent and protect against ovarian adhesions has utilized these materials as flat sheets of material which sheets were not well suited to the application to a rounded or dome-like organ such as the ovary.

Other attempts at enclosing an internal organ have involved the use of surgical pouches. For example, U. S. Patent 5,279,539 discloses a device and method for prevention of surgical adhesions, particularly ovarian adhesions, by endoscopic procedures utilizing a surgical drawstring pouch. The patentees suggest placing a surgical pouch over an ovary after a surgical procedure and then cinching the mouth of the pouch closed about the ovary to isolate the ovary from the surrounding body tissue. The pouch shown in this patent is bioabsorbable and is

capable of breaking down over a period of several months. The preferred material of the pouch is a warp knit fabric composed of oxidized regenerated cellulose (ORC) which may require neutralization to render it more compatible with body tissue. The surgical pouch of the '539 patent has two drawstrings. The first drawstring is detachable and is made up of resilient wire-like thread for maintaining the mouth of the pouch open during use. The second drawstring is intended to cinch the mouth of the pouch. The pouch is preferably placed over the ovary by an endoscopic procedure.

Thus, the prior art suggests various approaches to the problem of preventing post operative sequelae including the use of barriers to prevent adhesions. However, these barriers are either in sheet form or in the form of loose fabric pouches which degrade in the body. Therefore, there exists a need for an improved protective envelope or cover of biomaterial which can be applied to various organs, including the ovaries, which cover is molded or pre-shaped into the general shape of the organ. The cover should be adapted to be surgically implanted using conventional laparoscopic procedures.

Summary of the Invention

Accordingly, the present invention relates to the prevention of ovarian adhesions by the use of a cover fabricated of a non-resorbable material such as porous polytetrafluoroethylene. The commercially available material sold under the designation "Gore-Tex Surgical Membrane" as manufactured by W.L. Gore & Associates, Inc. of Flagstaff, Arizona. is a preferred material. The cover is pre-

formed by a suitable fabrication procedure such as heating and vacuum forming which locks the cover in the proper configuration. The cover includes a pouch which may take various shapes which will incorporate at least one compound curve and thereby encompass the configuration of an injured post operative organ such as the ovary. "Compound curve" as used herein means the state of being curved simultaneously in two perpendicular planes intersecting the curved region, whereby the cover incorporating the compound curves will encompass the configuration of an organ substantially without wrinkling as would normally occur if attempting to encompass such an organ with a flat sheet of flexible material which did not incorporate compound curves. The material of the cover has a nominal mean fibril length of about five microns or less to prevent tissue attachment. Preferably the pouch has a thickness in the range of 0.01 to 1.0 millimeters with 0.1 millimeters being preferred. The cover is configured as a pouch with a dome-shaped closed end that extends to a straight open-sided skirt. In a preferred embodiment, gathers which may be pleats or a series of notches, can also be provided in the skirt around the opposite, open mouth end. Slits can be provided to accommodate strands which serve as ties that will close the pouch over the ovary or other organ by drawing or cinching the slits together. The ties may be closed by tying one of the ties to the other or by securing the ties using laparoscopic ligaclips. The entire cover can be introduced at the surgical site laparoscopically through a trocar sleeve as, for example, a five millimeter diameter trocar sleeve which will allow it to be easily positioned over the damaged ovary. After a predetermined healing period.

typically from at least about 7 to 30 days, the pouch is surgically removed by laparoscopic procedures with minimum trauma to the patient.

Brief Description of the Drawings

The above and other objects and advantages of the present invention will be more fully appreciated from the following description, claims and drawings in which:

Figure 1 is a perspective view of an organ cover according to the present invention;

Figure 2 is a side elevation view of the cover as it is shown in Figure 1;

Figure 3 is a top view of the organ cover shown in Figures 1 and 2;

Figures 4 and 5 are diagrammatic representations showing the method of forming the cover of the present invention;

Figure 6 is a side view of the cover with the ties inserted in the pouch;

Figure 7 a view similar to Figure 6 in which the ties have been tensioned to close the pouch;

Figures 8 to 12 illustrate the surgical positioning of the cover by laparoscopic procedures;

Figure 13 is a top view of an alternate embodiment of the cover; and

Figure 14 is a side view of the cover of Figure 13.

Detailed Description of the Preferred Embodiment

Referring to Figures 1, 2, 6 and 7, the cover of the present invention is generally designated by the numeral 10. The cover 10 includes a pouch 12 which

is shown as having a domed closed end 14 and a circumferential side wall or skirt 16. The pouch 12 has an opening or mouth 18 opposite the closed end. The shape of the pouch 12 may vary to conform to the shape of the organ to which the cover is to be attached. The description of the invention will be with reference to the cover for application to an ovary, it being understood that the cover can be applied as a barrier to the formation of adhesions on other organs such as the uterus, fallopian tubes, spleen, pancreas and liver. The ovary, as the name implies, is generally oval in shape and is attached to a suspensory ligament. Thus the semi-oval bursiform configuration of the pouch is suited for ovarian applications. For other applications the pouch may be cup-shaped or otherwise configured as required by the particular application. The description of the pouch having at least one compound curve is intended to encompass these various shapes as well as other similar shapes.

The cover 10 has a peripheral edge 20 which extends around the mouth or opening 18. The peripheral edge is preferably provided with a series of vertically extending notches 24 which form a series of tabs 28 integral with the pouch. The tabs 28 extend partially around the periphery of the pouch starting near the rear of the cover as best shown in Figure 3. The tabs adjacent the rear of the pouch are of a height less than the corresponding tabs near the front of the pouch. The terms "front" and "rear" are relative terms used for purposes of orientation only with the rear of the pouch being the area designated by the letter "R" and the front being the area designated by the letter "F" in Figure 3. When individual tabs 28

are folded to extend generally at right angles with respect to the side wall 16 of the pouch, the slits open into V-shaped spaces as best seen in Figures 1 and 3.

Each of the tabs define a centrally extending slit 30 through which a tie may be threaded to facilitate closure of the pouch about the organ. The ties 32 and 34 are preferably strands cut from the material of the cover and are integral therewith and extend from the rear of the cover around the opposite sides of the pouch. Alternatively, separate ties may be used. In assembling the cover, the ties are threaded through the slits 30 as shown in Figure 6 which when tensioned, as shown in Figure 7, gathers the tabs in overlapping relationship and closes the mouth 18 of the cover.

The individual ties 32 and 34 are threaded through the slits 30 with the ends of the ties extending at the front of the pouch. One significant advantage of the design of the present invention is that the pouch is pre-formed to conform to the shape of the organ to which it is to be attached. An additional advantage is that the ties are an integral part of the structure so that the ties will not become detached from the pouch during surgical procedures. The result is a complex cover incorporating compound curves that is formed in the desired shape and is compatible with the configuration of the post operative organ such as an injured post-operative ovary.

The cover can be positioned by conventional surgical procedures such as endoscopy or standard laparoscopic procedures as seen in Figures 8 to 12. Endoscopic surgery involves the use of an endoscope which is an instrument

permitting the visual inspection and magnification of any cavity of the body. The endoscope is inserted through a tubular sheath referred to as a "cannula" after puncturing the wall of the body cavity with a trocar. The surgeon then performs the necessary procedures at the surgical site and with the aid of conventional instruments designed to fit through additional cannula. Similarly, the cover 10 can be inserted by laparoscopic instruments which is a type of endoscopy. A tube with an optical system is inserted through the abdomen to permit examination of the ovaries and the fallopian tubes. A trocar sleeve is inserted using laparoscopic instruments.

The porous PTFE cover of the present invention is flexible so it can be introduced through five millimeter or larger trocar sleeve 100 and can be easily maneuvered over the damaged ovary through the use of a standard instrument 106. Once inserted in the abdominal cavity, the cover 10 will tend to return to its pre-formed shape conforming to the shape of the ovary or other organ. The cover is placed with the pouch 12 over the ovary "O" in the manner shown in Figure 10. The ties 32, 34 are an integral part with the cover and will not become detached. Once the cover is in place, the surgeon will grasp the ties with instrument 106 and tension the ties 32 and 34 which will cause the mouth of the cover to close about the organ as seen in Figure 11. A ligating clip 115, as shown in Figure 12, or a suture may be used to retain the ties in place.

The procedure is relatively easy since the ties do not require threading but rather the threading has been accomplished prior to insertion of the pouch through

the trocar. The cover structure is integral in that no components remain which have to be later removed or which may become detached during the insertion procedure. In place, the cover envelopes a substantial portion of the surface of the ovary providing a significant benefit, protecting the ovary to reduce both the formation and severity of adhesions particularly in the area between the ovary and pelvic side wall. An advantageous characteristic of porous PTFE of adequately small pore size is that tissue does not readily attach to it. Thus, once the desired healing period has passed, the pouch can be surgically removed using endoscopic or laparoscopic procedures as described above. Generally the pouch will be left in place for a period of at least about 7 to 30 days. Use of a cover of the type according to the invention does not result in placement of an object which must be metabolized or otherwise eliminated from the body.

Figures 13 and 14 show an alternate embodiment of the present invention generally designated by the numeral 10A. The cover includes a pouch 12A having a domed, closed end 14A and a circumferential side wall or skirt 16A. The cover has a peripheral edge 20A which extends around mouth 18A without notches. Ties 32A and 34A extend through slits 30A formed at spaced intervals adjacent the edge. The embodiment 10A is fabricated and surgically positioned about an organ in the manner described above.

The fabrication of the cover 10 is accomplished by standard thermoforming techniques as seen in Figures 4 and 5. A blank sheet 50 of non-resorbable material is first clamped in a frame 52 to constrain its edges. The sheet 50 is

substantially impervious to tissue growth and tissue penetration which material is preferably a microporous membrane having a small pore size and a thickness in the range of 0.01 to 1.0 mm. A preferred material is porous PTFE such as that sold under the trademark "Gore-Tex Surgical Membrane". For a more complete discussion of this material, reference is made to U.S. Patent Nos. 4,478,665 and 4,187,390, herein incorporated by reference.

The restrained sheet 50 is positioned over suitable tooling such as a domed die 60 having the desired profile of the pouch. The material is heated to a temperature of at least 290°C by any conventional heat source 66, such as an oven or an infrared source. A vacuum is applied to the die 60 by vacuum source 62 resulting in a cover with the pouch formed and locked in the desired shape. The heat is removed and the material allowed to cool. The cover 10 is trimmed from the sheet by die cutting, stamping or otherwise severing to the completed shape as shown in Figure 1.

Example 1:

The following is a description of a method used to make a pouch from GORE-TEX® Surgical Membrane to fit a human ovary. The method utilized thermoforming techniques involving vacuum drawing over a male form having the shape of the domed die 60 described by Figures 4 and 5, useful for making a pouch of the shape generally described by Figures 1 - 3. The domed die was of 8 cm height; a horizontal cross section through the base of the domed die had a long axis dimension of 4.1 cm and a short axis dimension of 2.5 cm. This domed die

was made from 316 stainless steel of 2.0 mm thickness and was placed on a horizontally oriented vacuum plate 62 as shown by Figure 5.

A 12 X 12 cm sheet of porous PTFE (GORE-TEX Surgical Membrane, Part No. 1612012001, W.L. Gore & Associates, Inc., Flagstaff, AZ) was mounted in a perimeter frame to restrain the edges. A cylindrical air-convection oven of 15 cm inside diameter and 10 cm inside length was used to heat the sheet of porous PTFE. The length of the oven was vertically oriented; the top of the oven was a closed horizontal surface with two small, 5 mm diameter perforations to allow subsequent air flow. The bottom of the oven was left open. The oven was heated to an indicated temperature of 340°C. The restrained sheet of porous PTFE was placed across the bottom of the oven in a horizontal orientation so as to effectively become the lower surface of the oven. After one minute, the domed die, previously heated to about 75°C, was pressed into the sheet of porous PTFE which had become softened by the heat from the oven. The porous PTFE sheet conformed to the surface of the domed die and contacted the vacuum plate. 380 mm Hg of vacuum was applied to the vacuum plate, causing the sheet of porous PTFE to closely conform to both the domed die and the vacuum plate. The two small holes in the upper surface of the cylindrical oven allowed air flow during application of the vacuum. Immediately after initial application of the vacuum, the application of heat was discontinued and the porous PTFE covered domed die was allowed to cool by continued air flow from the supplied vacuum. After cooling to

about room temperature, the newly formed porous PTFE pouch was removed from the die. The pouch edges were trimmed to a desired shape using surgical scissors.

While the principles of the invention have been made clear in the illustrative embodiments set forth above, it will be obvious to those skilled in the art to make various modifications to the structure, arrangement, proportion, elements, materials and components used in the practice of the invention. To the extent that these various modifications do not depart from the spirit and scope of the appended claims, they are intended to be encompassed therein.

WE CLAIM:

CLAIMS

1. A cover for enclosing at least a portion of a body organ to reduce formation of adhesions, said cover comprising:

(a) a pouch of non-resorbable material preformed to a predetermined shape incorporating at least one compound curve wherein said shape generally corresponds to the shape of the organ to be enclosed;

(b) said pouch having an open mouth defined by a peripheral edge; and

(c) closure means for drawing the mouth of the pouch closed about the organ.

2. The cover of Claim 1 wherein said closure means comprises at least one tie integral with said pouch.

3. The cover of Claim 2 wherein said peripheral edge defines slits to receive said tie.

4. The cover of Claim 2 wherein said pouch is generally dome-shaped.

5. The cover of Claim 1 wherein said pouch is generally dome-shaped.

6. The cover of Claim 5 wherein said pouch comprises porous polytetrafluoroethylene.

7. The cover of Claim 6 wherein said porous polytetrafluoroethylene is porous expanded polytetrafluoroethylene having a microstructure of nodes interconnected by fibrils.

8. The cover of Claim 7 wherein the porous expanded polytetrafluoroethylene has a mean fibril length of about 5 microns or less.

9. The cover of Claim 8 wherein the porous expanded polytetrafluoroethylene has a thickness approximately between .01 mm and 1.0 mm.

10. The cover of Claim 1 wherein said pouch comprises porous polytetrafluoroethylene.

11. The cover of Claim 10 wherein said porous polytetrafluoroethylene is porous expanded polytetrafluoroethylene having a microstructure of nodes interconnected by fibrils.

12. The cover of Claim 11 wherein the porous expanded polytetrafluoroethylene has a mean fibril length of about 5 microns or less.

13. The cover of Claim 12 wherein the porous expanded polytetrafluoroethylene has a thickness approximately between 0.01 mm and 1.0 mm.

14. The cover of Claim 2 wherein said peripheral edge defines a plurality of tabs and said slits are defined in said tabs.

15. The cover of Claim 1 wherein said closure means is integral with said cover.

16. The cover of Claim 15 wherein said pouch comprises porous polytetrafluoroethylene.

17. A method of making a cover for enclosing at least a portion of an organ, said method comprising:

(a) placing a sheet of porous polytetrafluoroethylene over a die having a shape at least generally corresponding to the shape of the organ to which the cover is to be applied; and

(b) applying a vacuum to said die and heating said material to form a part of the sheet into a pouch in the desired shape.

18. The method of Claim 17 including trimming said material about said pouch to form a peripheral edge, said peripheral edge having at least one strand extending from and attached to the peripheral edge.

19. The method of Claim 18 further including the steps of forming tabs around the periphery of the cover and providing slits in said tabs adapted to receive said strands.

20. The method of Claim 19 wherein said strands are threaded through said slits.

21. The method of Claim 17 wherein said porous polytetrafluoroethylene is porous expanded polytetrafluoroethylene having a microstructure of nodes interconnected by fibrils.

22. The method of Claim 21 wherein said porous expanded polytetrafluoroethylene has a fibril length of about 5 microns or less.

23. The method of Claim 22 wherein said porous expanded polytetrafluoroethylene has a thickness of approximately between 0.01 mm and 1.0 mm.

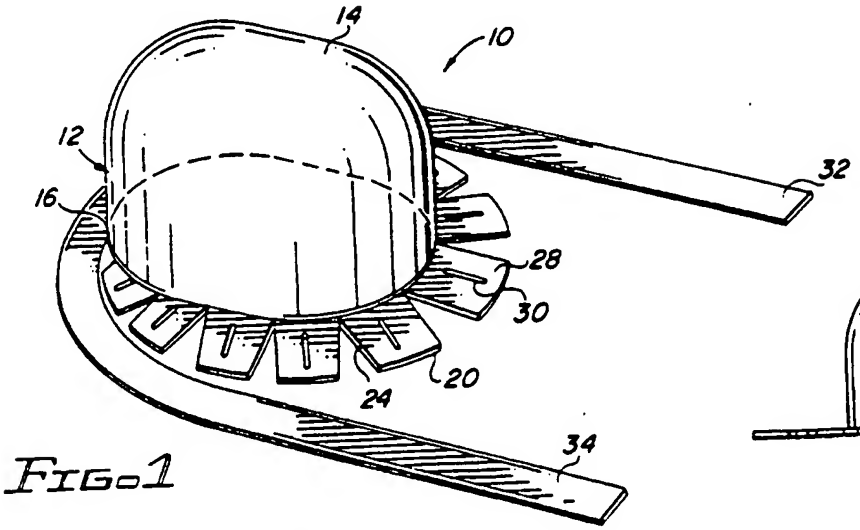

FIG. 1

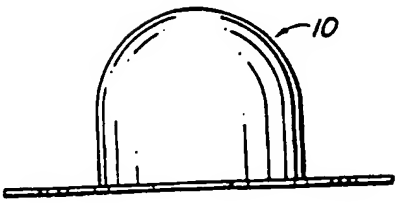

FIG. 2

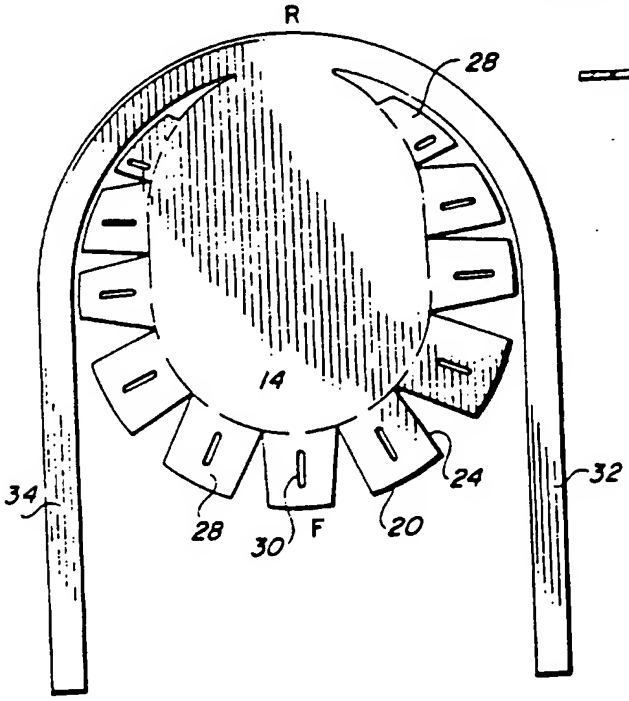

FIG. 3

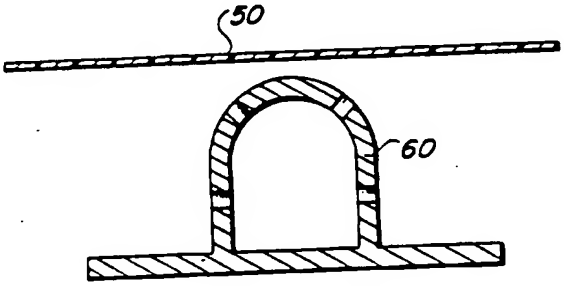

FIG. 4

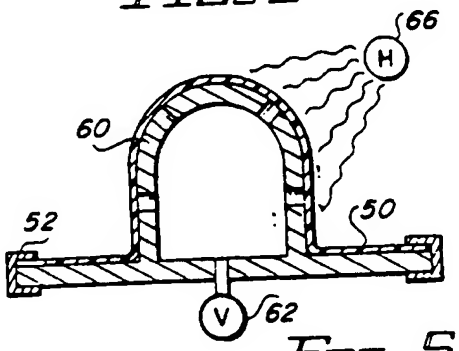

FIG. 5

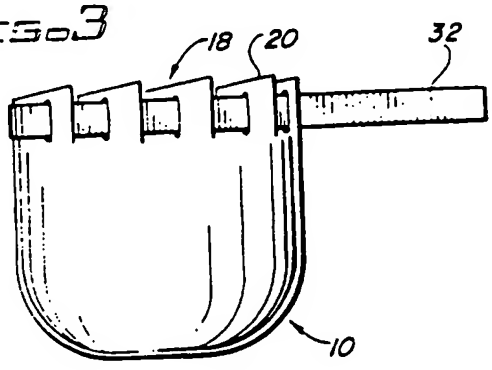

FIG. 6

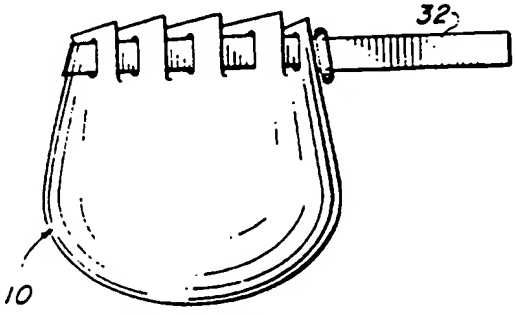

FIG. 7

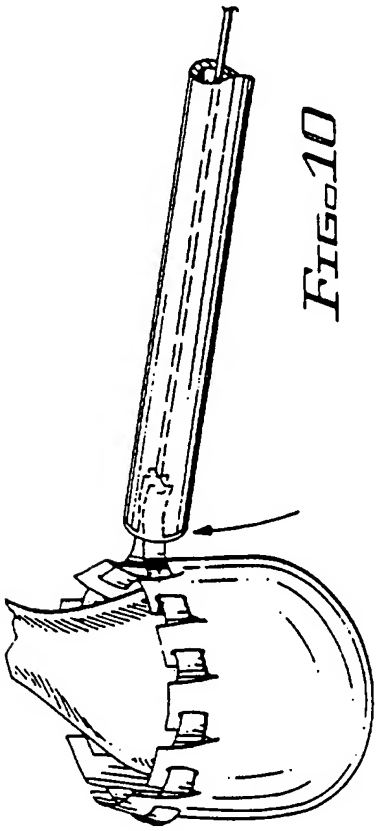

FIG. 10

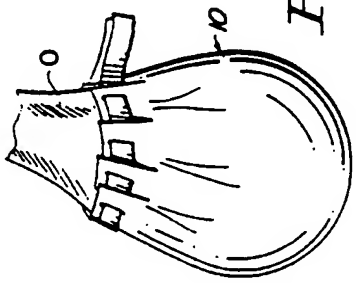

FIG. 11

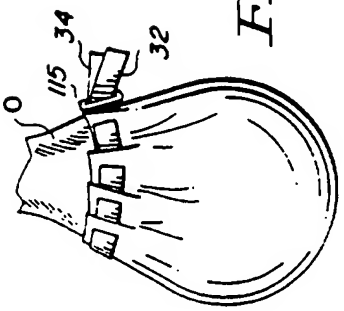

FIG. 12

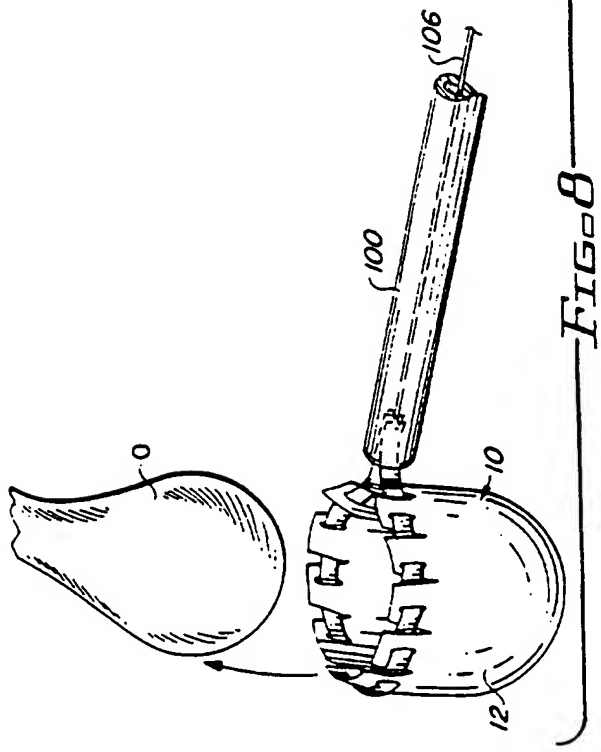

FIG. 8

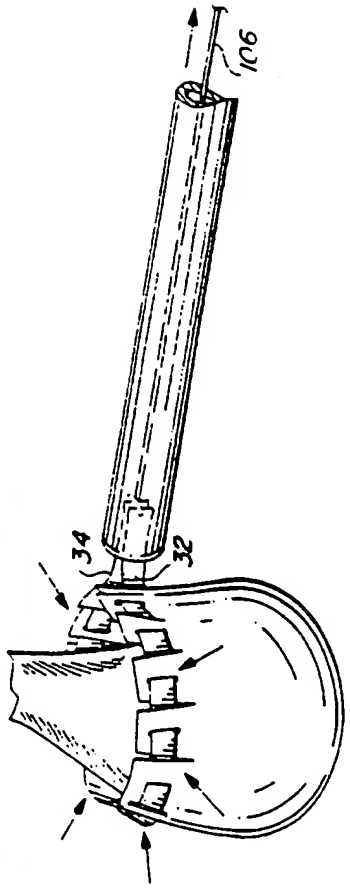

FIG. 9

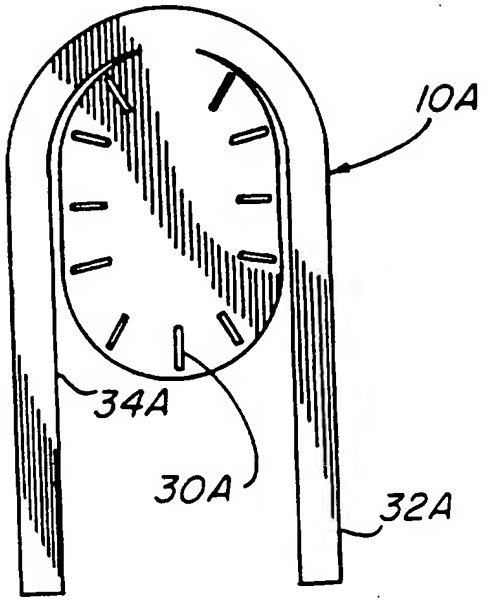

FIG. 13

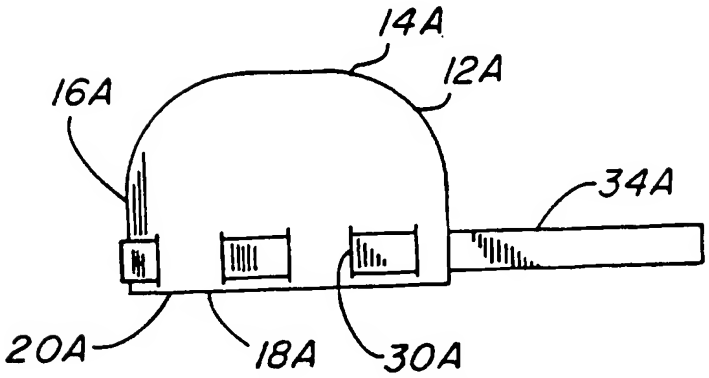

FIG. 14

INTERNATIONAL SEARCH REPORT

Inte. ...nal Application No
PCT/US 95/01171

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/00 A61F2/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	WO,A,88 09647 (CARINTHIA) 15 December 1988 see abstract; figures see page 5, paragraph 6	1,2,4,5, 15,17 6-13,16, 21-23
Y	EP,A,0 557 963 (UNITED STATES SURGICAL CORPORATION) 1 September 1993 see column 2, line 28-34; figures	6-13,16, 21-23
X	US,A,4 135 495 (BORGEN) 23 January 1979 see the whole document	1,2,4,5, 15
A	US,A,3 983 863 (WALKER) 5 October 1976	
A	US,A,5 279 539 (ETHICON) 18 January 1994 cited in the application	

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"O" document referring to an oral disclosure, use, exhibition or other means

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"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
21 July 1995	03. 08. 95

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+ 31-70) 340-3016	Steenbakker, J

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inte. onal Application No
PCT/US 95/01171

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
WO-A-8809647	15-12-88	DE-A-	3718557	22-12-88
EP-A-557963	01-09-93	CA-A-	2089999	25-08-93
		US-A-	5405360	11-04-95
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US-A-3983863	05-10-76	NONE		
US-A-5279539	18-01-94	EP-A-	0583964	23-02-94
		JP-A-	6154161	03-06-94